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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,881	06/27/2003	Bret A. Ferree	SP115.1	7244
25742	7590	03/23/2006		
JERROLD J. LITZINGER 2134 MADISON ROAD CINCINNATI, OH 45208			EXAMINER RAMANA, ANURADHA	
			ART UNIT 3733	PAPER NUMBER

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,881

Applicant(s)

FERREE, BRET A.

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 13 and 14 is/are rejected.
- 7) ☒ Claim(s) 1-7, 9-12 and 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/6/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

Figure 1 should be designated by a legend such as -- Prior Art -- because only that which is old is illustrated. See MPEP § 608.02(g).

The drawings are also objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following features must be shown or the features canceled from the claims:

- Claim 1 - the through slot in each of the first and the second plates
- Claim 6 – hollow interior and aperture in an end of the first and second plates
- Claim 11 – a plurality of channels in the first and second plates

No new matter should be entered.

Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the subject matter of claims 1, 6, 9, 10 and 11. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Although Applicant states on page 26 of the specification that features of various embodiments may be combined, the features of claims 6, 9, 10 and 11 are not described in the specification with respect to the embodiment of Figures 23A-23D being claimed by the Applicant.

On page 18, lines 18-25 and page 19, lines 1-15, Applicant must refer to "pivot 306" or "pivot points 306" as "pivot pins 306" to provide antecedent basis for claim terminology.

Appropriate correction is required.

Claim Objections

Claims 1, 2, 13 and 15 are objected to because of the minor informalities.

The following changes are suggested to avoid any possible ambiguity as to which pin and/or slot is being referred to claims 1 and 15.

Claim 1:

In line 3, insert - - first - - before "through" and "pivot" and "slot (second occurrence)" to refer to the pin and slot in the first plate.

In line 4, insert - - second - - before "through"

In line 5, insert - - second - - before "pivot" and "slot (second occurrence)" to refer to the pin and slot in the second plate.

In line 7, insert - - first - - before "through"

In line 10, insert - - second - - before "pivot"

In line 14, insert - - first and second - - before "through"

Claim 15:

In line 4, insert - - first - - before "through"

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In line 5, insert -- first -- before "slot"

In line 6, insert -- second -- before "through"

In line 7, insert -- second -- before "slot"

In claim 2, line 3, replace "unactuated" with -- in its unactuated position -- for clarity.

In claim 13, line 2, replace "at " with -- in -- and "portion" with -- position -- to correct minor typographical errors.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13 is rejected under 35 U.S.C. 101 because it is drawn to non-statutory subject matter. In claim 13, line 3, applicant positively recites part of a human, i.e. "held tightly in the cancellous bone of the vertebrae". Thus, the claim includes a human within its scope and is non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Applicant can overcome this rejection by reciting "each component is configured to be held tightly in the cancellous bone of the vertebrae."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 8 refers to a recess for accommodating a section of the opposing fixation device. However, the specification describes the fixation components as resting within slots 316 (Fig. 23C and page 19, lines 9-15 of Applicant's specification).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8, it is unclear how the first and second fixation components reside in a separate recess in each of the second and first plates, respectively, when the fixation components are in the unactuated position.

In claim 14, it is unclear what structure or structural relationship the Applicant is referring to by the limitation "comprise a contact line."

Allowable Subject Matter

Claims 1-7, 9-12 and 15-17 would be allowable if the minor objections made in this office action are addressed.

Claim 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter.

None of the prior art either alone or in combination teaches, discloses or suggests, Applicant's claimed invention of a prosthetic disc replacement device including: a first plate containing a first through slot and a first pivot pin spanning the first slot; a second plate containing a second through slot and a second pivot pin spanning the second slot; a first fixation component coupled to the first plate for rotation about the first pivot pin from an unactuated position within the interior of the device to an actuated position exterior to the device; a second fixation component coupled to the second plate for rotation about the second pivot pin from an unactuated position within the interior of the device to an actuated position exterior to the device; and an actuation member capable of insertion between the first and second plates to shift the first and second fixation components through the first and second through slots to the exterior of the device to affix the device between vertebrae.

None of the prior art either alone or in combination, teaches, discloses or suggests, a method of installing a prosthetic disc replacement device including the steps of: placing between the vertebrae of a spine a device, including a first plate containing a first through slot and a first fixation component rotatably coupled with the first slot, a second plate parallel to the first plate, the second plate containing a second through slot and a second fixation component rotatably coupled with the second slot; inserting an actuation member between the first and the second plates to shift the first and second fixation components out of the respective plates to affix the fixation components into adjacent vertebrae.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR 
March 19, 2006